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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,715

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Marie-Laure Fardeau

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

09/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,715	Applicant(s) FARDEAU ET AL.	
	Examiner TAEYOON KIM	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/7/2008 has been entered.

Applicant's amendment and response filed on 5/13/2008 has been received and entered into the case.

Claims 2-7 and 9-11 have been canceled, and claims 1, 8 and 12 are pending and have been considered on the merits. All arguments have been fully considered.

Information Disclosure Statement

In a miscellaneous letter filed on 7/23/2007, Applicant requested the examiner to consider a reference disclosed on the IDS filed on 6/10/2005. The examiner's initial was inadvertently omitted for the reference in the IDS, even though the reference (international search report of PCT/FR03/03665) has been already considered. A new copy of IDS with the correction has been attached to the current office action.

Response to Amendment

The claim objection to claims 8 and 12 in the previous office action has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §112, 2nd para., in the previous office action

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has been withdrawn due to the amendment.

The claim rejection under 35 U.S.C. §101 in the previous office action has been withdrawn due to the amendment.

The claim rejection in the previous office action under 35 U.S.C. §102 based on Drancourt et al. or Fruhling et al. has been withdrawn due to the amendment. However, the claim rejection under 35 U.S.C. §102 based on Farrow et al. is still maintained (see below).

Applicant's arguments have been fully considered, and based on the amendment in the current claims, the claim rejections have been withdrawn as indicated above, and thus the argument is moot. However, upon further consideration, new grounds of rejection are also made as below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation "a 16S rRNA sequence having more than 97% similarity to SEQ ID NO:1" in claim 1 does not have support in the as-filed specification. The

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insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the other species. There is only one exemplified strain in the specification. This is not sufficient support for the scope of the limitation “a 16S rRNA sequence having more than 97% similarity to SEQ ID NO:1.” The instant limitation broadens the scope of original disclosure. Thus, the insertion of “a 16S rRNA sequence having more than 97% similarity to SEQ ID NO:1” in the current claim is considered to be the insertion of new matter.

In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph, *Waldemar Link, GmbH & Co. v. Osteonics Corp.* 32 F.3d 556, 559, 31 USPQ2d 1855, 1857 (Fed. Cir. 1994); *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). See MPEP § 2163.06 - § 2163.07(b) for a discussion of the relationship of new matter to 35 U.S.C. 112, first paragraph. New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. See MPEP § 608.04 to § 608.04(c). See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) and MPEP § 2163.05 for guidance in determining whether the addition of specific percentages or compounds after a broader original disclosure constitutes new matter.

Claims 1, 8 and 12 are rejected under 35 U.S.C. § 112, first paragraph, as

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containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel biological materials, specifically *Exiguobacterium lactigenes* under the number I-2962. Since the biological materials are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the biological materials.

The specification does not disclose a repeatable process to obtain the biological materials, and it is not apparent if the biological materials are readily available to the public. It is noted that Applicant has deposited the biological materials (p.2, lines 33-38), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement

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by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit must be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §1.807) and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information; however, Applicant is cautioned to avoid entry of new matter into the specification by adding any other information.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Farrow et al. (1994; IDS ref.) in light of BLAST Basic local alignment search.

Claim 1 is interpreted as an isolated bacterial strain of a genus *Exiguobacterium* comprising a 16S rRNA sequence having more than 97% similarity to SEQ ID NO:1, and further comprising a DNA sequence capable of hybridizing with genomic or plasmid DNA of a strain deposited under the No. I-2926, and the isolated bacterial strain having properties listed in the claim.

Farrow et al. in light of BLAST and NCBI search results teach a bacterial strain (*Exiguobacterium aurantiacum*) designated as X70316.1. According to the NCBI search results, the 16S rRNA sequence of *Exiguobacterium aurantiacum* of Farrow et al. (X70316.1) has about 97.4% identity (thus, more than 97% similarity) with the 16S rRNA of AY818050. Since 16S rRNA of AY818050 strain is the same as SEQ ID NO:1, which is 16S rRNA of the claimed *Exiguobacterium lactigenes* with the deposit No. I-2962, it is concluded that the 16S rRNA sequence of the *E. aurantiacum* (X70316.1) of Farrow et al. has met the limitation of 16S rRNA sequence having more than 97% similarity to SEQ ID NO:1.

Since the 16S rRNA of *E. aurantiacum* taught by Farrow et al. is more than 97%

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similar to the strain of I-2926, it is an inherent property of *E. aurantiacum* of Farrow et al. to have a DNA sequence with a capability of hybridizing with genomic or plasmid DNA of the strain I-2962, particularly in the region of genomic DNA encoding 16S rRNA (i.e. 16S rRNA gene or 16S rDNA).

Although the strain of Farrow et al. is not named as the claimed strain, *Exiguobacterium lactigenes*, the mere difference in names would not make a known species novel. Even though the claimed strain of *Exiguobacterium lactigenes* is named differently from the strain (*Exiguobacterium aurantiacum*) of Farrow et al., a mere difference in names does not make the species patentable over prior art, especially in the absence of evidence to the contrary.

Farrow et al. is silent in the property of *Exiguobacterium aurantiacum* (X70316.1). However, since the 16S rRNA of the strain of Farrow et al. is significantly identical (98% identical) to the SEQ ID NO:1 of the current invention, and thus meets the limitation of the claimed invention, it is expected that the strain of Farrow et al. possesses the same properties as the claimed strain.

M.P.E.P. §2112 states that "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d

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1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.”

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' bacterial strain differs, and if so to what extent, from the bacterial strain discussed in Farrow et al. Accordingly, it has been established that the prior art bacterial strain, which meets the limitation of the claims, demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed bacterial strain that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of a known bacterial strain is not disclosed in a reference does not make the known bacterial strain patentable. The new bacterial strain possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the bacterial strain of the cited prior art do not possess a critical characteristic that is possessed by the claimed bacterial strain, would advance prosecution and might permit allowance of claims to applicants' bacterial strain.

M.P.E.P. §2112 states “Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as

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that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/ 103 rejection is appropriate for these types of claims as well as for composition claims.

Thus, the reference anticipates the claimed subject matter, or renders the claimed invention obvious.

Conclusion

No claims are allowed. Claims 8 and 12 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Examiner, Art Unit 1651